

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
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THIS DOCUMENT RELATES TO:)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (RWZ)
Suits Identified in the Exhibit to the)	
Tennessee Clinic Defendants' Previously-)	
Filed Global Motion to Dismiss [Dkt. 771])	
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**Reply of the Tennessee Clinic Defendants to
the PSC's Response to the Tennessee Clinic Defendants'
Global Motion to Dismiss**

Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”), Howell Allen Clinic, a Professional Corporation (“Howell Allen”), John W. Culclasure, M.D. (“Dr. Culclasure”), Debra V. Schamberg, R.N. (“Ms. Schamberg”), Specialty Surgery Center, Crossville, PLLC (“SSC”), Kenneth R. Lister, M.D. (“Dr. Lister”), and Kenneth Lister, M.D., P.C. (“Dr. Lister’s Practice”) (collectively “the Tennessee Clinic Defendants”) file this Reply to the Plaintiffs’ Steering Committee’s (“PSC”) Response to the Tennessee Clinic Defendants’ Global Motion to Dismiss.¹

¹ The original Global Motion to Dismiss is at Dkt. 771. In the Global Motion to Dismiss, the Tennessee Clinic Defendants moved to dismiss all claims against them as they fail to state a claim upon which relief can be granted. The Tennessee Clinic Defendants explained the reasons that the Plaintiffs’ claims fail in their Memorandum of Law in support of the original global Motion to Dismiss, at Dkt. 772. The PSC’s Response is at Dkt. 1040 (“PSC’s Resp.”). This pleading replies to the Response consistent with the briefing schedule at Dkt. 845-1.

1. Introduction

In 2012, NECC sold pharmaceutical products across the United States to health care providers, large and small.² In addition to a wide range of products sold to children's hospitals³ and university-based medical centers,⁴ NECC sold methylprednisolone acetate ("MPA"), the product at the center of this litigation, to health care providers at 145 locations in 26 states.⁵ NECC's national manufacturing operations were known to the Food and Drug Administration ("FDA"), which sanctioned NECC's manufacturing operations with regulatory inactivity.⁶ The scale of NECC's operations and lack of FDA intervention led to sloppiness and contamination of the MPA, resulting in the 2012 fungal meningitis outbreak and an ensuing rush of litigation.

Anticipating a petition in bankruptcy by NECC (which was filed on December 21, 2012), Plaintiffs' lawyers began attempting to transfer NECC's fault to health care providers who purchased product manufactured and distributed solely by NECC.

2. Conceded Claims

The Plaintiffs, in their Response, argue only for survival of their claims for (1) product liability as to STOPNC and SSC, (2) civil conspiracy, (3) "special duty," and (4) vicarious liability for NECC's actions.

² See, link at n. 32 of the PSC's Resp.:

<http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM326145.xls>, which is a searchable database of the thousands of health care facilities and providers who bought from NECC.

³ NECC's customers included the Children's Hospital of Boston, the Boston Children's Hospital at Waltham and North, and children's hospitals in Birmingham, New Orleans, East Tennessee, Chicago, Los Angeles, St. Paul, Phoenix, and Pittsburgh, as well as many others.

⁴ NECC's customers included Boston University Medical Center, Carolinas Medical Center, Columbia University Medical Center, Cooper University Hospital, Emory University Hospital, and Georgetown University Hospital, among others.

⁵ See link at n. 2, *supra*. for complete list of locations and states.

⁶ PRELIM. MAJ. STAFF REP., H.R. COMM. ON ENERGY & COMMERCE, 113TH CONG., FDA'S OVERSIGHT OF NECC AND AMERIDOSE: A HISTORY OF MISSED OPPORTUNITIES? (Apr. 16, 2013).

Therefore, the following claims should be dismissed without further argument:

1. Negligence/Gross Negligence;⁷
2. Product liability claim against Dr. Culclasure, Ms. Schamberg, or Dr. Lister;⁸
3. Product liability claim against Howell Allen or Dr. Lister's Practice;
4. Tennessee Consumer Protection Act;
5. Medical Battery; and
6. Informed consent claim against STOPNC, Howell Allen, Ms. Schamberg, SSC, and Dr. Lister's Practice.

3. Product Liability

a. The Health Care Liability Act governs the Plaintiffs' claims.

The Tennessee Clinic Defendants' Global Motion to Dismiss calls upon this Court to determine, and apply, the substantive law governing these claims. The moving Defendants respectfully insist that Tennessee's Health Care Liability Act ("HCLA"), Tenn. Code Ann. § 29-26-101, *et seq.*, the very latest pronouncement of the public policy of Tennessee,⁹ is *the* substantive law governing all of the Plaintiffs' claims against the Tennessee Clinic Defendants.

The Defendants' reasoning is straightforward. Each of the moving Defendants is a "health care provider" as defined by Tenn. Code Ann. § 29-26-101(2)(a). The

⁷ At page 24, footnote 94 of the PSC's Response, the Plaintiffs make a conclusory statement that claims for general negligence and failure to warn are "viable product liability theories." They offer zero legal support and no further explanation for this statement. Frankly, it makes no sense how these negligence-based claims could be "viable product liability theories," and it certainly does not justify them surviving a properly-supported motion to dismiss. *City of Bangor v. Citizens Communications Co.*, 532 F.3d 70, 95 n. 11 (1st Cir. 2008) (deeming waived argument "presented only in a passing fashion in a footnote").

⁸ The Plaintiffs' primary argument for application of the Products Liability Act to the claims against these Defendants is that the Defendant clinics charged for use of the product. As explained herein, that is factually and legally wrong. Notwithstanding the inaccuracy of the argument, the Plaintiffs concede at pages 18-19 of their brief that the physicians and physician groups (e.g., Howell Allen and Dr. Lister's Practice) billed solely for the *physician service*. In fact, that distinction forms the basis for the Plaintiffs' lead argument. As such, and by affirmative assertion of the Plaintiffs, the health care providers (Dr. Culclasure, Ms. Schamberg, Dr. Lister) and their groups (Howell Allen, Dr. Lister's Practice) did not act as "sellers" of any product. The product liability claims against them should be dismissed without dispute.

⁹ *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936) (citing canon of construction instructing that more recent statute trumps conflicting earlier statute); *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2348 (U.S. 2007) (internal citations omitted) (noting well-settled canon of statutory construction dictating that more specific statutory provision trumps a conflicting general statutory provision).

complaints against them claim injuries “related to the provision of, or failure to provide, health care services to a person...regardless of the theory on which the action is based.¹⁰ ¹¹ This fits the precise definition of a health care liability action.¹² Administration of a steroid into the epidural space by an anesthesiologist is clearly “related to” the provision of health care services, just like the delivery of an intracoronary stent by an interventional cardiologist or the placement of an artificial hip or knee by an orthopedic surgeon.¹³ The final section of the law leaves no doubt as to the scope of the Act: “Any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint....”¹⁴

The HCLA sets specific statutes of repose and limitation,¹⁵ pre-suit notice requirements,¹⁶ contemporaneous pleading requirements,¹⁷ competency standards for expert witnesses,¹⁸ and prohibits imposition of legal liability without proof of a departure from objective standards of professional practice in both the delivery of care¹⁹ and

¹⁰ TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added).

¹¹ The PSC alleges as much at ¶ 153 of the Master Complaint: “As part of this medical treatment, the Clinic Related Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs.”

¹² The PSC ignores this language and urges this Court to adopt its own illogical conclusion that “related to” health care services means “arising from” health care services. PSC’s Resp. p. 20. The PSC cites nothing to support its unilateral modification, glossing over the plain language of the statute and the fact that no known rule of construction supports such a conclusion.

¹³ Tennessee courts have historically held that cases related to the administration of medication are medical malpractice cases governed by the Medical Malpractice Act. See, e.g., *Sharkey v. O’Toole*, No. M2009-0112-COA-R3-CV, 2010 WL 3293925, at *1-*6 (Tenn. Ct. App. Aug. 19, 2010) (analyzing case in which the physician allegedly prescribed Haldol to a patient with a known Haldol allergy as medical malpractice case); *Taylor v. Jackson-Madison Cnty. Gen. Hosp. Dist.*, No. W2005-02471-COA-R3-CV, 2006 WL 2423456, at *1 (Tenn. Ct. App. Aug. 23, 2006) (analyzing case of allegedly negligent use of antibiotic, causing allergic reaction, as medical malpractice case).

¹⁴ TENN. CODE ANN. § 29-26-101(c).

¹⁵ TENN. CODE ANN. § 29-26-116.

¹⁶ TENN. CODE ANN. § 29-26-121.

¹⁷ TENN. CODE ANN. § 29-26-122.

¹⁸ TENN. CODE ANN. § 29-26-115(b).

¹⁹ TENN. CODE ANN. § 29-26-115(a).

obtaining informed consent.²⁰ The plain and simple language of the HCLA makes clear that strict liability in tort cannot be imposed against a health care provider.²¹

The PSC argues otherwise, misstating the law of Tennessee and ignoring applicable rules of statutory construction.

- b. The 1993 modification of the statute of limitations for claims against manufacturers of breast implants did not – contrary to the PSC’s contention – make health care providers strictly liable in tort for all other products used in the delivery of health care services.**

In 1992, the FDA held highly publicized hearings on the safety of silicone gel breast implants in more than one (1) million women, triggering a rush to courthouses across the country.²² On May 18, 1993, the Tennessee Legislature passed Chapter 457, Senate Bill 196. Implication from what is *not* said in the bill is the centerpiece of the PSC’s argument that health care providers are strictly liable in tort for damages from defective products used in the delivery of health care services.

Tennessee employs well-established rules of construction to ascertain legislative intent when the meaning of the language employed is uncertain. Application of these rules of construction exposes the failure of the Plaintiffs’ argument.

One rule focuses on the words of the legislators.²³ Senator Thelma Harper, the primary sponsor of the 1993 bill to lengthen the statute of limitations for breast implant claims, spoke directly and conclusively to the bill’s intent:

[The bill] does not have to do with medical malpractice, that’s not what this issue is about; it has to do with a product.²⁴

²⁰ TENN. CODE ANN. § 29-26-118.

²¹ TENN. CODE ANN. § 29-26-115; TENN. CODE ANN. § 29-26-118.

²² See *In Re Silicone Gel Breast Implant Products Liability Litigation*, 793 F. Supp. 1098, 1098 (J.P.M.L. 1992).

²³ *Mills v. Fulmarque, Inc.*, 360 S.W.2d 362, 368 (Tenn. 2012).

²⁴ Statement of Sen. Thelma Harper, S. FINANCE, WAYS, AND MEANS COMM., 14:01 – 14:10 (Apr. 27, 1993). Audio file filed with the Court as Exhibit A.

Second, the Tennessee Constitution provides that:

No bill shall become a law which embraces more than one subject, that subject to be addressed in the title. All Acts which repeal, remove or amend former laws, shall recite in their caption or otherwise, the title of the law repealed, removed or amended.²⁵

Drawn from this provision of the Constitution, another accepted rule of construction instructs courts interpreting Tennessee statutes to look to the caption of the act to discern the legislative intent.²⁶ The caption of the 1993 Act expressly declares it “an Act to amend Tennessee Code Annotated, Section 29-28-103, relative to limitation of actions.”²⁷ Extending the statute of limitations for claims against “manufacturers or sellers” of breast implants does not convey a goal to make physicians strictly liable in tort for all products used in the delivery of medical services.²⁸ Attempting such an extension would blatantly violate the Tennessee Constitution.

Third, the Legislature is presumed to know the state of the law at the time it passes legislation,²⁹ and, in determining legislative intent, the courts are also to consider existing public policy.³⁰ As a result, the process of determining the intent of ambiguous legislation “must seek a reasonable construction which avoids statutory conflict and provides for harmonious operation of the laws.”³¹

Tenn. Code Ann. § 47-2-316(5) has been law since 1967, 26 years before the Legislature amended the Tennessee Products Liability Act’s statute of limitations to

²⁵ TENN. CONST. art. II, § 17.

²⁶ *Hyatt v. Taylor*, 788 S.W.2d 554, 556 (Tenn. 1990); *Shelby County Healthcare v. Nationwide Mut. Ins. Co.*, 325 S.W.3d 88, 97 (Tenn. 2010).

²⁷ S.B. 196, 93rd Gen. Assemb., 1993 Sess. (Tenn.) (emphasis added). Copy attached as Exhibit B.

²⁸ Courts should not broaden a statute beyond its intended scope, as shown by the plain, and ordinary meaning of the language. *Thurmond v. Mid-Cumberland Infectious Disease Consultants, PLLC*, 2014 WL 1632183 at *4 (Tenn. Apr. 24, 2014).

²⁹ *Sullivan v. Chattanooga Med. Investors*, 221 S.W.3d 506, 511 (Tenn. 2007).

³⁰ *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 527-28 (Tenn. 2010).

³¹ *LensCrafters, Inc. v. Sundquist*, 33 S.W.3d 772, 777 (Tenn. 2000).

create an exception for cases related to breast implants.³² The unambiguous text of § 47-2-316(5) makes clear that the “transplanting, injection, transfusion or other transfer of such substances³³ into the human body shall be considered a medical service” for which health care providers cannot be liable without fault. In 1972, 21 years before the amendment to the statute of limitations on silicone gel breast implant claims, the Tennessee Court of Appeals, relying upon Tenn. Code Ann. § 47-2-316(5), concluded that a medical service was *not a sale* subject to the Products Liability Act.³⁴

In 1992, the year prior to the 1993 amendment to the statute of limitations for breast implant claims, the Tennessee Supreme Court dramatically revised the law of Tennessee, sweeping away the doctrines of contributory negligence and joint and several liability, and adopting modified comparative fault.³⁵ Modified comparative fault imposes liability upon a defendant “only for the percentage of damages his fault has caused.”³⁶ The law expressly authorizes assertion of fault against non-parties, so as to prevent a jury’s allocation of responsibility to a defendant for culpability that lies elsewhere.³⁷

Furthermore, the Supreme Court of Tennessee has *expressly rejected* the argument of the PSC that the health care providers must bear the liability of NECC because NECC is insolvent:

³² The text of § 47-2-316(5) also proves that the PSC is completely in error to assert that the modification in the statute of limitations for breast implant claims against manufacturers and sellers is the “one and only circumstance in which health care providers are not considered product sellers.” PSC’s Resp. p. 12, nn. 56-57. The Legislature did not amend § 47-2-316(5) by amending the statute of limitations on breast implant claims, demonstrating that the PSC is wrong in contending that health care providers are sellers, strictly liable in tort, for every product used in conjunction with medical services except breast implants.

³³ Described in Tenn. Code Ann. § 47-2-316(5) to include human tissues, such as corneas, bones, or organs, and whole blood, plasma, blood products, or blood derivatives.

³⁴ *St. Martin v. Doty*, 493 S.W.2d 95, 97 (Tenn. Ct. App. 1972).

³⁵ *McIntyre v. Ballentine*, 833 S.W.2d 52 (Tenn. 1992).

³⁶ *Id.* at 58.

³⁷ *Carroll v. Whitney*, 29 S.W.3d 14, 20 (Tenn. 2000).

[W]e decline to adopt a rule comparable to the rule under the Uniform Comparative Fault Act pursuant to which the liability of a given defendant is enhanced beyond the defendant's percentage of fault if another culpable defendant is insolvent. We do not believe that the goal of linking liability with fault is furthered by a rule that allows a particular defendant's liability to be determined by the happenstance of the financial wherewithal of other defendants.³⁸

Thus, Tennessee's courts, citing this state's public policy, reject liability without breach of a duty of care, and limit recoverable damages to the percentage of fault applicable to each defendant, even when another culpable defendant is insolvent.

Against this background, it is ludicrous to suggest that the Legislature set out to override the game-changing 1992 comparative fault decision in *McIntyre* and silently repeal a portion of the Medical Malpractice Claims Act³⁹ to make health care providers *strictly liable* for defects in every product or device – except silicone gel breast implants – provided in conjunction with health care services. It is even more ludicrous to suggest the Legislature intended to accomplish all this without saying so,⁴⁰ under the cloak of an amendment to the statute of limitations for silicone gel breast implant claims. The Legislature does not intend absurd results, nor should courts construing legislation.⁴¹ Legislators likewise do not “hide elephants in mouseholes[,]” as the PSC would have the Court believe.⁴²

³⁸ *Volz v. Ledes*, 895 S.W.2d 677, 680 (Tenn. 1995). Nearly twenty (20) years later, in *Lake v. The Memphis Landsmen*, the Court again rejected the contention of the PSC that the first objective of the law is to compensate plaintiffs, stating “the preference in Tennessee is to protect a defendant from liability greater than his or her proportional fault, even though such protection may come at the expense of the plaintiffs.” 2014 WL 895519, at *7 (Tenn. Ct. App. Mar. 7, 2014) (slip op.).

³⁹ Repeals by implication are disfavored. *Cronin v. Howe*, 906 S.W.2d 910, 912 (Tenn. 1995).

⁴⁰ The Tennessee Supreme Court has frequently commented that the cardinal rule of construction to determine and carry out legislative intent comes from examination of the “natural and ordinary meaning of the language used, without a forced or subtle construction that would limit or extend the meaning of the language.” *Penley v. Honda Motor Co.* 31 S.W.3d 181, 185 (Tenn. 2000) (emphasis added) (internal quotations omitted).

⁴¹ *State v. Sims*, 45 S.W.3d 1, 11 (Tenn. 2001).

⁴² *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001).

c. Health care providers did not sell the injected steroid, and the Defendants are not subject to strict liability.

The PSC insists that the Tennessee health care providers should be treated the same as an intermediate wholesaler, distributor, or retailer since NECC is bankrupt and insolvent. The argument misses the mark in four (4) material respects.

First, no matter how many times the PSC says it, the Tennessee health care providers simply *did not sell* MPA to patients. Tennessee law distinguishes between administration of a medication and sale of a medication.⁴³ A licensed physician *administered* MPA by injection into the epidural space, as expressly authorized by the law of Tennessee.⁴⁴ Tenn. Code Ann. § 29-28-102 limits the definition of a seller to one engaged “in the business of selling a product.”⁴⁵ “Health care,” defined in Tennessee as “any care, treatment, service⁴⁶ or procedure, to maintain, diagnose, treat or otherwise affect an individual’s physical or mental condition,”⁴⁷ by contrast, has long been considered a *service* in Tennessee.⁴⁸ Health care services simply are *not* a product and have never been considered a product under Tennessee law.⁴⁹

Second, the Plaintiffs contend that STOPNC and SSC billed separately for the MPA, a “fact” that purportedly establishes them as sellers exposed to strict product

⁴³ See TENN. COMP. R. & REGS. 0880-02-14(2)(a)-(d) (2010).

⁴⁴ Master Compl. ¶ 153.

⁴⁵ TENN. CODE ANN. § 29-28-102(7).

⁴⁶ Contrary to the argument of the PSC, health care is clearly not limited only to “service.”

⁴⁷ TENN. COMP. R. & REGS. 1200-08-10.01(29) (2014). Notably, the definition is not limited purely to services alone, and does not exclude the ancillary delivery of tangible products in the service.

⁴⁸ See *Olson v. Molzen*, 558 S.W.2d 429 (Tenn. 1977). This Court should be aware of the overall statutory scheme in Tennessee. Treating or operating upon a patient requires licensure as a physician. TENN. CODE ANN. § 63-6-204. Even if licensed, a physician cannot administer spinal injections as a part of interventional pain management unless she is board certified in a specific medical specialty, meets specific exceptions to the board certification requirements, or administers the injections in a licensed facility. TENN. CODE ANN. § 63-6-244. A retailer, distributor, or wholesaler of products need not meet any of these requirements.

⁴⁹ A product is a tangible object or good produced. TENN. CODE ANN. § 29-28-102(5).

liability.⁵⁰ However, that “fact” is not consistent with the law or documentation cited in the complaints. Regardless, notably absent from the Plaintiffs’ brief is citation to *anything* supporting the leap from (1) billing for medication to (2) strict product liability.⁵¹

The Plaintiffs attempt to create a distinction between the professional service fees charged by Howell Allen (a neurosurgical group) and STOPNC (an ambulatory surgery center or “ASC”), where no distinction exists. The Plaintiffs assert that, because Howell Allen charged for the physician’s services, it follows that STOPNC’s separate charge⁵² must have been for the \$6.50 vial of MPA used during the procedure.

Foremost, no exercise of common sense could lead to the conclusion that STOPNC (or SSC) billed these patients’ insurers \$1,034.00 for a \$6.50 vial of MPA.⁵³⁵⁴ Further, the Court need only look to the CMS regulations codifying the components of an ASC’s facility fee to gut the Plaintiffs’ argument. The *title* of the applicable regulation succinctly demonstrates that the facility fee is for *health care services*, *not* a separate charge solely for the medication:

Coverage, Scope of **ASC Services**, and Prospective Payment System for **ASC Services** Furnished on or After January 1, 2008.⁵⁵⁵⁶

⁵⁰ PSC’s Resp. pp. 18-20.

⁵¹ *Id.* at 18-19.

⁵² The fee charged by health care facilities is colloquially referred to as a “facility fee.”

⁵³ *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (U.S. 2009) (noting that the analysis at the motion to dismiss stage requires application of common sense).

⁵⁴ Likewise, the Plaintiffs ignore the fact that the fee billed did not increase when patients received more than a single dose of MPA. To use the example chosen by the PSC in its Response, Diana Reed received an 80 mg dose of MPA (a single vial) on August 21, 2012, and received a 120 mg dose of MPA (a vial and a half) on September 4, 2012, but the facility fee charged by STOPNC did not change. If the facility fee were truly a charge for the steroid, as contended by the PSC, the fee logically would have increased. These facts are explicitly pled in the *Reed* complaint but conveniently ignored in the PSC’s Response. *Reed* Compl. ¶¶ 169, 170, 233.

⁵⁵ 42 CFR pt. 416, subpart F (emphasis added).

⁵⁶ The applicable regulations consistently refer to “services” as the subject of the reimbursement. E.g., 42 CFR §§ 416.160(a)(1), 416.160(a)(2), 416.160(a)(4), 416.160(b)(1), 416.160(b)(2), etc.

The regulations in this subpart set forth numerous specific examples of professional health care services included in an ASC's facility fee, including nursing services, technician services, use of the facility, use of the equipment, administrative services, housekeeping services, and recordkeeping services.⁵⁷ The Plaintiffs even explicitly allege in their complaints that they received many of these services while at STOPNC, such as the use of the facility,⁵⁸ nursing services,⁵⁹ and administrative services.⁶⁰ As the regulatory framework demonstrates, the provision of services is what the facility fee is for, *not* a sale of medication, as the Plaintiffs claim.

Third, the PSC ignores the fact that Tennessee will not apply different substantive standards to a single transaction. Instead, courts must look to the predominant aspect of the transaction to determine the applicable substantive law.⁶¹ The relationship between the Plaintiffs and STOPNC is one based predominately, if not entirely, on the delivery of health care services.⁶² That common sense conclusion leads directly to the determination that this is a "health care liability action"⁶³ governed by the substantive provisions of the HCLA, *not* the Products Liability Act.

⁵⁷ 42 CFR § 416.164 (emphasis added).

⁵⁸ All Plaintiffs allege their injections occurred at STOPNC. *Reed Compl.* ¶ 5 (Case No. 1:13-cv-12565-RWZ).

⁵⁹ The Plaintiffs allege that the care and treatment of STOPNC's nurses was negligent. *Reed Compl.* ¶ 249.

⁶⁰ Any number of the Plaintiffs' allegations could be considered to concern "administrative services," including the failure to promptly notify the Plaintiffs regarding the outbreak. *Reed Compl.* ¶ 172.

⁶¹ *Hudson v. Town & Country True Value Hardware*, 666 S.W.2d 51, 53 (Tenn. 1984).

⁶² "As part of this medical treatment, the Clinic Related Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs." *Master Compl.* ¶ 153 (emphasis added).

⁶³ Defined at Tenn. Code Ann. § 29-26-101(a)(1).

Finally, the Tennessee Court of Appeals decision in *Burris*⁶⁴ and the Tennessee Supreme Court decision in *Komatsu*⁶⁵ effectively conclude the argument that product liability theories do not apply to the claims against Tennessee health care providers.

In 1989, four (4) years before the 1993 revision of the product liability statute of limitations for claims arising from silicone gel breast implants, the Tennessee Court of Appeals expressly held that the Medical Malpractice Review Board and Claims Act of 1975, the precursor to the HCLA, encompassed product liability claims arising from allegedly defective products implanted into a patient.⁶⁶ Tennessee's subsequent enactment of the *much* broader HCLA reinforced this ruling.

Twelve years later in *Komatsu*, Tennessee adopted § 5 of the RESTATEMENT (THIRD) OF TORTS, limiting a manufacturer's liability.⁶⁷ The same RESTATEMENT (THIRD) OF TORTS, adopted in *Komatsu*, unequivocally informs this Court's decision.⁶⁸

Courts are unanimous in refusing to categorize commercially-provided services as products for the purposes of strict liability in tort. Thus, strict products liability does not extend to professionally-provided services, such as medical or legal help.⁶⁹

...

Hybrid cases often arise in the medical context, as when a surgeon uses defective forceps during an operation. Most jurisdictions hold that hospitals and

⁶⁴ *Burris v. Hosp. Corp. of Am.*, 773 S.W.2d 932 (Tenn. Ct. App. 1989).

⁶⁵ *Davis v. Komatsu American Indus. Corp.*, 42 S.W.3d 34 (Tenn. 2001).

⁶⁶ *Burris*, 773 S.W.2d at 935.

⁶⁷ *Komatsu*, 42 S.W.3d at 40-41.

⁶⁸ Tennessee cases that adopt or at least seek guidance from the RESTATEMENT are too numerous to cite. A search of the Tennessee appellate case law database for mentions of the "Restatement" returns over 1,500 cases. When faced with a gap in Tennessee law, Tennessee courts often adopt the approach set forth by the RESTATEMENT. See, e.g., *Jones v. State*, No. M2012-02546-SC-S09-CV, 2013 WL 6795237, *6 (Tenn. Dec. 23, 2013) (adopting RESTATEMENT (SECOND) OF TORTS position on immunity from defamation claims); *Cullum v. McCool*, No. E2012-00991-SC-R11-CV, 2013 WL 6665074, *5 (Tenn. Dec. 18, 2013) (citing to former case that adopted RESTATEMENT (SECOND) OF TORTS description of duty of business owners in premises cases).

⁶⁹ RESTATEMENT (THIRD) OF TORTS § 19 cmt. f (emphasis added).

doctors provide a service – medical treatment – and immunize them from strict liability for harm from defective products used in medical treatment[.]⁷⁰

The Tennessee Clinic Defendants did not sell a “product”⁷¹ to the Plaintiffs. Instead, health care services were provided, which included administration of MPA compounded by NECC. If the Tennessee Clinic Defendants are at fault, that determination can only be made based on satisfaction of the substantive liability provisions of the HCLA.⁷²

d. The Plaintiffs do not even offer a response to the Defendants’ other points.

The Plaintiffs simply offer little or no response to the following arguments, instead urging the Court to infer an all-encompassing change in the law from a sub-exception to an exception to the statute of limitations for product liability:

1. Twenty-six (26) of 28 states that have considered this exact issue have decided it contrary to the position put forth by the Plaintiffs.⁷³ The Plaintiffs cite zero case law from Tennessee or outside Tennessee to support their position.⁷⁴
2. Tennessee courts have explicitly held that the Tennessee Consumer Protection Act does not apply to health care providers since they provide professional medical services.⁷⁵

⁷⁰ RESTatement (THIRD) OF TORTS § 20 cmt. d (emphasis added).

⁷¹ Defined as a tangible object or good produced. TENN. CODE ANN. § 29-28-102(5).

⁷² TENN. CODE ANN. § 29-26-115. Tennessee uniformly utilizes the standard of acceptable professional practice to judge the conduct of health care providers. For ambulatory surgery centers licensed in Tennessee, whether they provided drugs or biologicals appropriately is measured by “accepted standards of practice.” TENN. COMP. R. & REGS. 1200-8-10-06(1)(b), (5). Accepted standards of practice also govern the provision of drugs and biologicals in office-based surgeries. TENN. COMP. R. & REGS. 0880-02-.21(d)(7).

⁷³ With the original Motion, the Defendants filed an exhibit that identified 23 states that have decided the issue. Continued research has uncovered **Louisiana**, *Huffaker v. ABC Ins. Co.*, 659 So.2d 544, 545-46 (La. Ct. App. 1995) (holding based on medical malpractice statute explicitly incorporating claims against health care providers based on defective products); **Colorado**, *St. Luke’s Hosp. v. Schmaltz*, 534 P.2d 781, 784 (Col. 1975); and **North Carolina**, *Batiste v. American Home Prod. Corp.*, 231 S.E.2d 269, 272-73 (N.C. Ct. App. 1977), as states that have also decided the issue.

⁷⁴ Perhaps more telling, the Plaintiffs do not cite, and the Defendants have not located, any case in Tennessee in which a health care provider was held strictly liable for use of a defective product. If the Plaintiffs are correct regarding the applicability of the Product Liability Act to health care providers, one would expect to locate at least one such example in the thirty-six (36) years since Tennessee enacted the statute.

⁷⁵ *Constant v. Wyeth*, 352 F. Supp. 2d 847, 853-54, n. 10 (M.D. Tenn. 2003).

3. Tennessee law recognizes that health care providers are engaged in the business of rendering services, *not* selling goods, for tax purposes.⁷⁶
4. Sound public policy weighs against extending strict product liability to health care providers. Strict liability would require health care providers to begin carrying product liability insurance for each of the hundreds, if not thousands, of medications they administer, not to mention countless other medical supplies. Imposition of strict liability would make medical providers insurers of every item they use. The cost of this would inevitably be passed on to patients, further increasing the already high cost of health care.^{77 78}

4. Civil Conspiracy

The Plaintiffs attempted to save their civil conspiracy claim by filing the First Amendment to the Master Complaint.⁷⁹ However, the claim fails because the Plaintiffs *still* fail to plead facts to support the elements of civil conspiracy and that establish a causal nexus between the alleged conspiracy and the injury.

Claims for civil conspiracy “must be pled with some degree of specificity,” and “[c]onclusory allegations...unsupported by material facts will not be sufficient to state [a claim for civil conspiracy].”⁸⁰ The Tennessee Supreme Court defines civil conspiracy as a “combination of two or more persons who, each having the *intent* and knowledge of the other's intent, accomplish by concert an unlawful purpose, or accomplish a lawful purpose by unlawful means, which results in damage to the plaintiff.”⁸¹

⁷⁶ TENN. COMP. R. & REGS. 1320-5-1-.26(1) (2008); see also *In Re: Memphis Kidney & Dialysis Services*, No. P-140905 T-A, at p. 2 (Tenn. State Bd. of Equalization, Admin. Judge for Shelby County, Tenn., Mar. 17, 2003) (“The testimony of Memphis Kidney & Dialysis Services’ administrator establishes that the company is predominantly engaged in the delivery of medical services. Though billed separately for whatever drugs they may receive in connection with those services, Memphis Kidney & Dialysis Services’ clients are essentially paying for dialysis treatment and related services.”). Opinion attached as Exhibit C.

⁷⁷ *Ayyash v. Henry Ford Health Sys.*, 210 Mich. App. 142, 146-47 (Mich. Ct. App. 1995).

⁷⁸ Interestingly, the PSC, in filing its response to the motion to dismiss filed by the Premier Defendants, argues the opposite of its position here, taking the stance that the claims against the clinics are “medical malpractice” matters for negligent provision of “medical services.” See Dkt. 980, pp. 6-7.

⁷⁹ Dkt. 832.

⁸⁰ *Kincaid v. SouthTrust Bank*, 221 S.W.3d 32, 38 (Tenn. Ct. App. 2006) (citing *McGee v. Best*, 106 S.W.3d 48, 64 (Tenn. Ct. App. 2002) (internal citations omitted)); see also *In re Estate of Storey*, No. W2010-00819-COA-R3-CV, 2011 WL 2174901, at *28 (Tenn. Ct. App. Oct. 15, 2010).

⁸¹ *Trau-Med of America, Inc. v. Allstate Ins.*, 71 S.W.3d 691, 703 (Tenn. 2002).

a. The Plaintiffs do not allege an actionable underlying tort.

In addition to the above elements, civil conspiracy requires an actionable, underlying predicate tort.⁸² Where the predicate tort is not actionable, the conspiracy is not actionable.⁸³ Even if the Plaintiffs properly allege a violation of a statute or regulation by these Defendants (which they do not⁸⁴), none of these statutes or regulations provides a private right of action. Accordingly, the Plaintiffs fail to allege an actionable tort supporting a civil conspiracy claim.⁸⁵ Civil conspiracy does not create a right of action where otherwise none exists.⁸⁶

Thus, the only conceivable, actionable tort alleged by the Plaintiffs' conspiracy allegations is fraud, although it is unclear whom the defrauded party was.⁸⁷ Intent to defraud is a necessary element of a civil conspiracy *where the alleged conspiracy is to defraud*.⁸⁸ The Plaintiffs do not dispute they failed to plead that the Defendants intended to defraud them. They argue that intent to defraud is not a required element, but fail to put forth any other actionable underlying tort. Indeed, even assuming the Clinic Defendants violated the cited regulations (a stretch), violations of the regulations do not provide the Plaintiffs with an underlying tort cause of action.

⁸² *Watson's Carpet & Floor Coverings, Inc. v. McCormick*, 247 S.W.3d 169, 180 (Tenn. Ct. App. 2007).

⁸³ *Id.* at 179-80.

⁸⁴ The Tennessee Clinic Defendants will not address Mass. Gen. Law Ch. 94C, § 17(c), cited for the first time in the PSC's Response. PSC's Resp. p. 32. The Plaintiffs misleadingly cite to ¶ 372 of the First Amendment to the Master Complaint as if the statute were cited in that paragraph, but it is not cited there or anywhere else in the Master Complaint or First Amendment. *Id.* at 32, n. 156. Regardless, a violation of Ch. 94C, § 17(c) fails as an "actionable underlying tort" for civil conspiracy because it likewise does not provide a private right of action.

⁸⁵ See *Brown v. Tennessee Title Loans, Inc.*, 328 S.W.3d 850, 863 (Tenn. 2010) (granting a defendant's motion to dismiss for failure to state a claim because the statutory violation alleged by the plaintiff did not support a private right of action).

⁸⁶ See *id.*

⁸⁷ Master Compl. ¶ 338.

⁸⁸ *Chenault v. Walker*, 36 S.W.3d 45, 52 (Tenn. 2001) (Civil conspiracy requires "common purpose, supported by a concerted action to defraud, that each [conspirator] has the intent to do it, that it is common to each of them, and that each has the understanding that the other has that purpose." *Dale v. Thomas H. Temple Co.*, 186 Tenn. 69, 90 (1948)).

b. The Plaintiffs fail to plead that the Defendants intended to accomplish an unlawful purpose or accomplish a lawful purpose by unlawful means.

The Plaintiffs conclusively allege that the Tennessee Clinic Defendants conspired with NECC to unlawfully violate the prescription requirements of Tennessee, the federal government, and the Massachusetts Board of Pharmacy.⁸⁹ However, the facts pled, even if taken as true, do not allege the requisite intent.

The Plaintiffs specifically plead that the Tennessee Clinic Defendants believed providing patient lists to NECC served to “*comply with Massachusetts Board of Pharmacy requirements.*”^{90 91} The Plaintiffs state that an NECC representative informed STOPNC that any list of patient names would suffice to *comply* with Massachusetts Board of Pharmacy requirements.⁹² In addition, the Plaintiffs attach a handwritten note by Ms. Schamberg demonstrating that Ms. Schamberg believed NECC requested patient lists to *comply* with Massachusetts law.⁹³

Put simply, the Plaintiffs allege, on the part of the Tennessee Clinic Defendants, an effort to engage in conduct intending to act *lawfully*. Ms. Schamberg could not have both intended to act unlawfully and, at the same time, intended to comply with the law. As a result, the Plaintiffs fail to plead sufficient facts to support a claim that the Defendants intended to act unlawfully. The Plaintiffs instead plead the exact opposite – an intent to act lawfully.

⁸⁹ First Am. to Master Compl. ¶ 385.

⁹⁰ *Id.* ¶ 379 (emphasis added).

⁹¹ In Tennessee, where Ms. Schamberg is licensed to practice, the law permits compounders to compound medications prior to receiving prescriptions. TENN. CODE ANN. § 63-10-204(4)(b) (2007) (providing that compounding includes preparing drugs “in anticipation of prescription orders based on routine, regularly observed prescribing patterns[.]”).

⁹² First Am. to Master Compl. ¶ 379.

⁹³ Ex. 3 to First Am. to Master Compl.

c. The Plaintiffs' civil conspiracy claim lacks causation.

Despite the First Amendment to the Master Complaint, the Plaintiffs *still* fail to plausibly explain how the alleged civil conspiracy caused the Plaintiffs' injuries.⁹⁴ The Plaintiffs absurdly argue that if the Defendants had sent patient-specific prescriptions to NECC, NECC would not have been able to compound medications in bulk.⁹⁵

This Court must exercise common sense in deciding a motion to dismiss.⁹⁶ The statutes and regulations governing patient-specific prescriptions, which the Defendants allegedly conspired to violate, required only that NECC *dispense* medications pursuant to a patient-specific prescription. They did not affect whether NECC could *compound* medications in bulk. Sending 100 individual patient prescriptions rather than a single list of 100 patient names would not have prevented NECC from compounding in bulk and sending the same contaminated product. To allege that failing to provide patient-specific prescriptions caused the injuries fails the "but for" causation test and any test for proximate cause. Accordingly, the Plaintiffs fail to establish the requisite causal nexus.

5. "Special Duty" – The Plaintiffs' "special duty" claim fails because the Plaintiffs fail to allege any facts to support a finding of duty.

The Plaintiffs cite *Turner v. Jordan*⁹⁷ and *Limbaugh v. Coffee Medical Center*,⁹⁸ in support of their creation of the "special duty" claim. But, these cases instead demonstrate the *lack of duty* in the case at bar. Both cases are addressed in detail in the Defendants' Memorandum of Law in Support of their Motion to Dismiss and will not be rehashed here. The important point ignored by the Plaintiffs is that, in both *Turner*

⁹⁴ *Trau-Med.*, 71 S.W.3d at 703.

⁹⁵ PSC's Resp. p. 33.

⁹⁶ *Iqbal*, 129 S. Ct. at 1950.

⁹⁷ 957 S.W.2d 815 (Tenn. 1997).

⁹⁸ 59 S.W.3d 73 (Tenn. 2001).

and *Limbaugh*, the only cases finding a similar “special duty,” the defendant had *actual knowledge*, thus making the harm foreseeable and supporting a finding of a heightened duty.⁹⁹

The existence of a legal duty is “entirely a question of law for the court.”¹⁰⁰ “[A] decision by the court that, upon any version of the facts, there is no duty, must necessarily result in judgment for the defendant.”¹⁰¹ The court must determine a duty exists by first establishing that the risk of harm was foreseeable.¹⁰² The Tennessee Supreme Court has held that foreseeability is “paramount to the analysis of duty.”¹⁰³

Here, unlike *Turner* and *Limbaugh*, the Plaintiffs allege *no* facts indicating the Tennessee Clinic Defendants had actual knowledge that made the contamination of the medications foreseeable.¹⁰⁴ The Plaintiffs’ only factual allegation supporting the Tennessee Clinic Defendants’ alleged “special duty” is the conclusive statement that “well-known dangers of bulk pharmacy compounding” made the contamination foreseeable.¹⁰⁵ However, Plaintiffs fail to plead any specific facts explaining how these alleged “well-known dangers” made *this* contamination foreseeable. They do not allege the Tennessee Clinic Defendants knew of past instances of contamination by NECC, NECC’s past failures to comply with sterility practices, or specific instances of regulatory action against NECC for contamination. This failure is fatal to the Plaintiffs’ novel “special duty” claim.

⁹⁹ See *Turner*, 957 S.W.2d at 816-17; see *Limbaugh*, 59 S.W.3d at 76-77.

¹⁰⁰ *Bradshaw v. Daniels*, 854 S.W.2d 865, 869 (Tenn. 1993).

¹⁰¹ *Giggers v. Memphis Housing Auth.*, 277 S.W.3d 359, 365 (Tenn. 2009) (internal citations omitted).

¹⁰² *Id.* at 365.

¹⁰³ *Id.* at 366.

¹⁰⁴ *Pellicone* Compl. ¶¶ 191-99 (Case No. 1:13-cv-12916-RWZ).

¹⁰⁵ *Id.* at ¶¶ 193-94.

6. Vicarious liability / Agency

a. The Plaintiffs do not proffer any law to support a finding of an agency relationship under Tennessee law.

The Plaintiffs criticize the factors the Defendants suggested the Court use to determine whether an agency relationship existed, without proposing an alternative. The absurd suggestion that agency law applies to a health care provider simply purchasing from a drug company makes it impossible to find a case directly on point. Tennessee does not apply agency law in this context. The Plaintiffs, again, ask the Court to step out on a limb and create a new theory of liability found nowhere in Tennessee law. However, any reasonable agency analysis the Court chooses yields the same result.

As noted in the RESTATEMENT (SECOND) OF AGENCY (1958), the primary consideration in evaluating an agency relationship is the principal's ability to exercise control over the agent.¹⁰⁶ The Plaintiffs fail to plead that the Tennessee Clinic Defendants exercised any control over NECC. The sole allegation pertaining to control states, "The Clinic Related Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Plaintiffs."¹⁰⁷ But, NECC did not procure the MPA; the Tennessee Clinic Defendants did. Essentially, the Plaintiffs allege that the Defendants controlled themselves when they were procuring the medication, which, of course, is true. However, the Plaintiffs allege no facts to support any notion that the Tennessee Clinic Defendants controlled NECC.

¹⁰⁶ *McInturff v. Battle Ground Academy of Franklin*, No. M2009-00504-COA-R3-CV, 2009 WL 4878614, at *3 (Tenn. Ct. App. Nov. 5, 2009).

¹⁰⁷ Master. Compl. ¶ 335.

Additionally, Tennessee courts recognize that a finding of control must extend beyond controlling the *result* of the agent's work.¹⁰⁸ The principal must control the *means* of obtaining that result.¹⁰⁹ The Plaintiffs allege no facts to support any notion that the Tennessee Clinic Defendants controlled NECC's *process* of compounding of drugs, such as selecting the source of raw materials, imposing policies and procedures, or establishing or setting NECC's compounding method or formula.¹¹⁰

To the contrary, the allegations of the Master Complaint plainly show it would have been impossible for the Tennessee Clinic Defendants to exercise such control. The Master Complaint affirmatively alleges that NECC sold MPA from the three contaminated lots to more than 70 different health care providers scattered across the country.¹¹¹ Logic dictates that all 70 Clinic Related Defendants could not possibly have simultaneously exercised control over the compounding at issue.

The Plaintiffs have alleged no facts to support any reasonable conclusion that the Tennessee Clinic Defendants *controlled* NECC or NECC's compounding process. This is essential to the agency claim. Without it, the claim fails.

7. Conclusion

Thousands of health care providers from across the country, large and small, rural and urban, sophisticated and unsophisticated, purchased medication from NECC,

¹⁰⁸ *Carbide & Carbon Chem. Corp. v. Carson*, 239 S.W.2d 27, 31 (Tenn. 1951).

¹⁰⁹ *Id.*

¹¹⁰ The lack of specific allegations of control is particularly striking in light of the fact that the Plaintiffs had roughly six months before filing the Master Complaint to review every communication between NECC and STOPNC; Howell Allen; Dr. Culclasure; and Ms. Schamberg. STOPNC was sued in state court in early 2013 and produced and/or described the substance of all documents and communications with NECC before the Plaintiffs voluntarily dismissed the cases in June 2013. Those Plaintiffs refiled their suits in federal court and are now part of the MDL. Those Plaintiffs, and many others, attached as exhibits to their complaints, portions of the Defendants' interrogatory responses and various other documents produced. See *Reed Compl.*, Exhibits J-Q. If there were facts demonstrating control, they would have been pled.

¹¹¹ Master Compl. ¶ 22.

assured by its promise of compliance with industry standards. NECC then cut corners and contaminated medications, sickening hundreds. The Plaintiffs have settled their claims, rightfully, against NECC and its affiliates, for over \$100 million.

Now, the PSC asks the Court to create new law and extend strict product liability to these health care providers even though such an extension is unapproved by any Tennessee court, unsupported by the facts pled, contrary to sound public policy, at odds with the stated legislative intent of the cited laws, in contravention of the near-universal American rule, and inconsistent with all relevant case law, statutory law, regulatory law, and respected legal treatise. Doing so would be, quite literally, unprecedented.

Doing so would open the floodgates to strict product liability claims against health care providers for all products used incidental to services, from cotton swabs to medications, from IV fluids to syringes, even to food hospitals serve to patients; and, it would be done based only on a strained reading of an exception to an exception to the statute of limitations for breast implants, a law passed 20 years ago without the slightest suggestion the Legislature intended such a broad-reaching change to the law.

Likewise, the Plaintiffs ask the Court to rubber stamp causes of action for civil conspiracy to intentionally *comply* with the law, for failure to protect patients from unforeseeable actions of a third-party, and for principal-agent liability where the Defendants clearly had *no* control over the actions of the purported agent. These theories, like that for product liability, fail the most basic tests of legal viability.

For the foregoing reasons, the Court should dismiss the Plaintiffs' product liability, negligence/gross negligence, special duty, agency, civil conspiracy, medical battery, Tennessee Consumer Protection Act, and lack of informed consent claims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 7th day of May, 2014.

/s/ Chris Tardio

Chris Tardio

¹¹² Admitted pursuant to MDL Order No. 1.

¹¹³ Admitted *pro hac vice*.